07 CV 6341

File #242221-06/ag

JUDGE LEISURE

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

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TEDDY W. HUDDLESTON, as Administrator of the Estate of GARY WAYNE HUDDLESTON, Deceased,

Plaintiff,

-against-

FOREST LABORATORIES, INC., FOREST PHARMACEUTICALS, INC. and INWOOD LABORATORIES, INCORPORATED,

Defendants.

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COMPLAINT

Plaintiff Demands Trial by Jury

Plaintiff, by attorneys, FINKELSTEIN & PARTNERS, LLP, as and for the Verified Complaint herein alleges upon information and belief the following:

STATEMENT OF THE CASE

1. Plaintiff, TEDDY W. HUDDLESTON, as Administrator of the Estate of GARY WAYNE HUDDLESTON, Deceased, brings this action under the laws of the State of Virginia, Va. Code Ann. § 8.01-50 et seq. (Wrongful Death), and § 8.01-25 et seq. (Survival Action), to recover damages for the wrongful death of , and personal injuries to, plaintiff's decedent, sustained as the direct and proximate result of the wrongful conduct of Defendants, FOREST LABORATORIES, INC., FOREST PHARMACEUTICALS, INC., (also referred to collectively as "Forest"), and INWOOD LABORATORIES, INCORPORATED, in connection with the designing, developing, manufacturing, distributing, labeling, advertising, marketing, promoting, and selling of the prescription drug Celexa, and the prescription drug Citalopram HBr

(hereinafter "Citalopram"), the generic form of Celexa, which was marketed and sold by Defendant, INWOOD LABORATORIES, INCORPORATED.

JURISDICTION AND VENUE

2. Jurisdiction exists as against Defendants, FOREST LABORATORIES, INC., FOREST PHARMACEUTICALS, INC., and INWOOD LABORATORIES, INCORPORATED, pursuant to:

(a) 28 U.S.C. Section 1332, in that Plaintiff, TEDDY W. HUDDLESTON, as Administrator of the Estate of GARY WAYNE HUDDLESTON, Deceased, is a citizen and resident of the State of Virginia, at the time of his death, plaintiff's decedent, GARY WAYNE HUDDLESTON, was a citizen and resident of the State of Virginia, Defendant, FOREST LABORATORIES, INC., is incorporated in the State of Delaware and maintains its principal place of business in the State of New York, Defendant, FOREST PHARMACEUTICALS, INC., is incorporated in business in the State of Delaware and maintains its principal place of business in the State of Missouri, and Defendant, INWOOD LABORATORIES, INCORPORATED, is incorporated in the State of New York and maintains its principal place of business in the State of New York, and the amount in controversy exceeds the sum of $75,000.00 exclusive of interest and costs.

(b) 28 U.S.C. Section 1391, in that jurisdiction is founded only on diversity of citizenship, and Defendants, FOREST LABORATORIES, INC., FOREST PHARMACEUTICALS, INC., and INWOOD LABORATORIES, INCORPORATED, are subject to personal jurisdiction in the Judicial District of the Southern District of New York and may be deemed to reside in the Southern District of New York.

PARTIES

3. The above-named plaintiff's decedent, GARY WAYNE HUDDLESTON, was the son and next of kin of the Plaintiff above-named, TEDDY W. HUDDLESTON, and on and prior to the 12th day of July, 2005, the deceased and Administrator resided in Bedford County, State of Virginia.

4. That prior to the commencement of this action, Plaintiff, TEDDY W. HUDDLESTON, was granted Certificate/Letters of Qualification, by the Clerk of the Circuit Court of Bedford County of the Commonwealth of Virginia, appointing him Administrator with respect to the estate of the deceased, GARY WAYNE HUDDLESTON, on the 8th day of September, 2005, and at all times hereinafter mentioned, duly qualified and entered upon his duties as such Administrator and is now acting in such capacity. A copy of said Certificate is attached hereto.

5. At the time of death on July 12, 2005, plaintiff's decedent was then of the age of 35 years and prior thereto, was generally in good health, industrious and possessed all faculties.

6. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., was and still is a foreign corporation organized under the laws of the State of Delaware.

7. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., was and still is a foreign corporation authorized to do business in the State of New York.

8. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., was and still is a business entity actually doing business in the State of New York.

9. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., was and still is a foreign corporation organized under the laws of the State of Delaware.

10. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., was and still is a foreign corporation authorized to do business in the State of New York.

11. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., was and still is a business entity actually doing business in the State of New York.

12. At all times hereinafter mentioned, upon information and belief, Defendant, INWOOD LABORATORIES, INCORPORATED, was and still is a domestic corporation organized under the laws of the State of New York.

13. At all times hereinafter mentioned, upon information and belief, Defendant, INWOOD LABORATORIES, INCORPORATED, was and still is a foreign corporation authorized to do business in the State of New York.

14. At all times hereinafter mentioned, upon information and belief, Defendant, INWOOD LABORATORIES, INCORPORATED, was and still is a business entity actually doing business in the State of New York.

15. At all times hereinafter mentioned, upon information and belief, Defendant, INWOOD LABORATORIES, INCORPORATED, was and still is a subsidiary of FOREST LABORATORIES, INC.

16. At all times hereinafter mentioned, upon information and belief, Defendant, INWOOD LABORATORIES, INCORPORATED, markets generic products as a subsidiary of FOREST LABORATORIES, INC.

17. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Celexa, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

18. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Celexa, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

19. A all times hereinafter mentioned, upon information and belief, Defendant, INWOOD LABORATORIES, INCORPORATED, is engaged in the business of designing, manufacturing, advertising, marketing, and selling pharmaceutical drugs, including Citalopram, and in pursuance of this business, transacts business within the State of New York and contracts to provide goods and services in the State of New York.

20. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Virginia.

21. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Virginia.

22. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

23. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST LABORATORIES, INC., expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

24. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Virginia.

25. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Virginia.

26. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

27. At all times hereinafter mentioned, upon information and belief, Defendant, FOREST PHARMACEUTICALS, INC., expects or should reasonably expect its acts to have

consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

28. At all times hereinafter mentioned, upon information and belief, Defendant, INWOOD LABORATORIES, INCORPORATED, committed a tortious act inside the State of New York, which caused injury to plaintiff's decedent inside the State of Virginia.

29. A all times hereinafter mentioned, upon information and belief, Defendant, INWOOD LABORATORIES, INCORPORATED, committed a tortious act outside the State of New York, which caused injury to plaintiff's decedent inside the State of Virginia.

30. At all times hereinafter mentioned, upon information and belief, Defendant, INWOOD LABORATORIES, INCORPORATED, regularly does and solicits business and engages in a persistent course of conduct in the State of New York, deriving substantial revenue from goods and products consumed in the State of New York.

31. At all times hereinafter mentioned, upon information and belief, Defendant, INWOOD LABORATORIES, INCORPORATED, expects or should reasonably expect its acts to have consequences in the State of New York, and derives substantial revenue from interstate or international commerce.

32. At all times relevant hereto, Defendants, FOREST LABORATORIES, INC., and FOREST PHARMACEUTICALS, INC., manufactured, produced and marketed Celexa, also known as Citalopram, one of the drugs in the family of selective serotonin reuptake inhibitors ("SSRIs").

33. At all times relevant hereto, Defendant, INWOOD LABORATORIES, INCORPORATED, manufactured, produced and marketed Citalopram, the generic form of Celexa, one of the drugs in the family of selective serotonin reuptake inhibitors ("SSRIs").

34. In the last decade there has been a host of peer-reviewed scientific literature linking the SSRI drugs, of which Celexa and/or Citalopram are two, to violence – both self-directed and directed towards others.

35. The Citalopram marketed by Defendant, INWOOD LABORATORIES, INCORPORATED, is a Forest authorized generic, meaning an exact copy of the Forest-branded product Celexa.

36. The INWOOD LABORATORIES, INCORPORATED generic, Citalopram, is approved for sale by the Food & Drug Administration under the same New Drug Application (NDA) as the branded Forest product.

FACTS

37. Plaintiff's decedent, GARY WAYNE HUDDLESTON, was born on December 4, 1969.

38. Prior to May 2005, plaintiff's decedent was diagnosed with bipolar disorder and depression.

39. On May 3, 2005, plaintiff's decedent's physician prescribed to plaintiff's decedent 20 mg Celexa or Citalopram tablets, to be taken once a day.

40. Between May 10, 2005 and July 2005, plaintiff's decedent's physician prescribed plaintiff's decedent 20 mg Celexa or Citalopram tablets, to be taken twice a day.

41. Between approximately July 2005, until plaintiff's decedent's death on July 12, 2005, plaintiff's decedent's prescription was reduced to 10 mg of Celexa or Citalopram, to be taken once a day.

42. Plaintiff's decedent's physician prescribed Celexa or Citalopram because he believed that Celexa and Citalopram were effective in treating depression in adults, an opinion

based upon research that had been distributed by Defendants. However, this medication did not help the condition for which it was prescribed.

43. Celexa and Citalopram are orally administrated psychotropic drugs that Defendants have marketed as if each was a single, highly selective medicine which has the ability to treat a host of maladies.

44. Defendants do not know exactly how or why Celexa and Citalopram elevate the mood of some individuals. Defendants just believe that the drugs work well to a "statistically significant" degree in a population of depressed adult patients.

45. Since the early 1980s, Defendants have been aware of serious and life threatening side effects to individuals who take Celexa and its generic form Citalopram, especially children and adolescents who take Celexa and Citalopram.

46. Initially, Citalopram (plaintiff's decedent's prescriptions for Celexa or Citalopram during this time were filled by the generic Citalopram) seemed to help with plaintiff's decedent's mood, depression, and mental condition.

47. Within two months after taking Citalopram, however, plaintiff's decedent reported suicidal thoughts. Plaintiff's decedent's physician continued to prescribe Celexa or Citalopram, although at a reduced dosage.

48. On July 12, 2005, plaintiff's decedent committed suicide by way of self-inflicted gun shot. He was 35 years old.

49. Defendants have been aware for many years that persons who are prescribed Celexa or Citalopram are much more likely to commit self-directed violence and even attempt suicide.

50. Defendants sell Celexa and Citalopram in the United States under a license with H. Lundbeck, a Danish company that developed Celexa.

51. Prior to July 2002, there had been "reasonable evidence of an association" between serotonergic drugs and akathisia, the serotonin syndrome, and violence/suicide.

52. Prior to July 2002, drug companies like Defendants insisted that, unless/until someone absolutely proved a causal relationship, that they would not warn physicians or the public about the dangers of SSRIs.

53. Prior to July 2002, Defendants were aware that children and adolescents who were prescribed Celexa and/or the generic Citalopram and other SSRIs, were much more likely to commit self-directed violence and were at an increased risk of suicidal behavior.

54. Even though Defendants were aware of this information, they withheld this information from various government agencies and the public at large, all the while knowing that physicians were prescribing Celexa and/or the generic Citalopram to children and adolescents throughout the world.

55. It is now well-known, and it was known to Defendants at the time Celexa or the generic Citalopram was prescribed to plaintiff's decedent, that there was a significant increase in depression, suicidal ideation, and suicide among children and adolescents taking Celexa or the generic Citalopram.

56. Dr. J. John Mann, an expert retained by GlaxoSmithKline, coauthored a paper in which he discusses the phenomenon of iatragenic suicide and postulates that there may well be a "small vulnerable subpopulation" of patients for whom SSRIs pose a paradoxical risk of suicide or aggression.

57. In a 1991 paper titled "The emergence of suicidal ideation and behavior during antidepressant pharmacotherapy" and again in 1992 in "Suicidal behavior and psychotropic medication," Dr. Mann laid out four study protocols which could be used by SSRI manufacturers to test the hypothesis that SSRIs pose a risk of violence and suicide for a "small vulnerable subpopulation" of patients. The tests would have either proven or disproven the causal relationship. However, Defendants chose not to conduct these prospective tests. Nor have Defendants bothered to publish the internal studies that they did regarding Celexa and/or the generic Citalopram and aggression.

58. In the last decade, including dates prior to July 2002 there has been a host of peer-reviewed scientific literature linking SSRIs to violence in minors – both self-directed and other directed. Such literature includes finding in the early 1990s from world class experts, including Teicher & Cole, Mann & Kapur, Wirshing & Van Putten, and Dr. David Healy and his colleagues in the UK, warning about the rise of SSRI-induced akathisia in violence and suicide.

59. In 2000 a peer reviewed article was published by Donovan and colleagues reporting on an epidemiological study, funded in part by SSRI manufacturers Eli Lilly and SmithKline Beecham. The article reports that, to a statistically significant degree, with a "p-value" of .001, the incident of deliberate self-harm of people on SSRI medications is 5.5 times higher than that of people on the more traditional tricyclic antidepressants. Donovan, et al., "*Deliberate Self-Harm and Antidepressant Drugs: Investigation,*" British J. Psych. 2000 Dec; 177 (6): 551-56, table 3.

60. In June 2000, the latest edition of the Diagnostic and Statistics Manual, *i.e.* the DSM-IV-TR was published. Section 333.99 of that revision lays out the causal link between SSRIs and akathisia and thence to either violence or suicide.

61. In June of 2002, the American Journal of Psychiatry, a journal that has 37,000 readers, reported test results for Celexa, indicating it could help children and teenagers who suffer from depression.

62. Before publication, the article received the kind of scrutiny common among medical journals. The study's authors had been asked to divulge their financial ties, if any, to the drug's marketer, Forest Laboratories, which sponsored the clinical trial. The report was sent to reviewers who examined the trial methodology and checked to make sure that the article reflected other relevant research about the use of antidepressants in youngsters.

63. Neither the article, nor the 27 footnotes that accompanied it, mentioned another major drug-industry-sponsored trial completed in 2002, which found that Celexa did not help depressed adolescents any more than a placebo. Nor would the article's reviewers have been likely to find any clues of that trial's existence.

64. The results of that trial were first noted last year on a single line of a chart that appeared on Page 96 of a textbook - one written in Danish.

65. The hidden Celexa trial was run in Europe from 1996 to 2002 and was sponsored by H. Lundbeck.

66. A spokesman for Lundbeck has stated that the company reported the trial results to Forest Laboratories, who kept the negative trial results hidden from the public.

67. Forest and Lundbeck have stated that an article about that trial was being prepared for publication two years after completion.

68. Dr. David Healy published a paper in 2003 titled "Lines of Evidence on the Risks of Suicide with Selective Serotonin Reuptake Inhibitors." Dr. Healy concludes that based upon his review of randomized clinical trials (RCTs), there was a "possible doubling of the relative

risk of both suicide and suicide attempts on SSRIs compared with older antidepressants or non-treatment...."

69. In a similar paper by Dr. Peter R. Breggin in 2003 titled "Suicidality, violence and mania caused by selective serotonin reuptake inhibitors (SSRIs): A review and analysis," Dr. Breggin concludes that "evidence from many sources confirms that [SSRIs] commonly cause or exacerbate a wide range of abnormal mental and behavioral conditions." In addition, Dr. Breggin describes such adverse drug reactions to include "mild agitation to manic psychoses, agitated depression, obsessive preoccupations that are *alien or uncharacteristic* of the individual and akathisia" (emphasis added).

70. In early 2004, FDA drug-safety analyst Andrew Mosholder was assigned to review some SSRI trials and noticed that a number of events that looked like suicide attempts had been subsumed under the term "emotional lability." After conducting his own analysis, Mosholder concluded that "children on [SSRIs] were almost twice as likely to experience suicidal thoughts or exhibit suicidal behavior as those taking placebos."

71. On February 2, 2004, the Psychopharmacological Drugs Advisory Committee (PDAC) and the Pediatric Subcommittee of the Anti-Infective Drugs Advisory Committee held an advisory committee meeting, to discuss reports of the occurrence of suicidality in clinical trials for various antidepressant drugs in pediatric patients with major depressive disorder.

72. At that time in February 2004, the FDA announced a request to the manufacturers of ten antidepressant drugs, including Defendants for Celexa and/or the generic Citalopram, that they strengthen the "Warnings" section of the package insert to encourage close observation for worsening depression or the emergence of suicidal thinking and behavior in both adult and

pediatric patients being treated with these agents, particularly for depression but also for other psychiatric and non-psychiatric disorders.

73. In March 2004, the FDA warned US doctors of an increased risk of suicidality with SSRI drugs, specifically identifying Celexa and Lexapro, which are two very similar drugs sold by Forest under a license with their developer H. Lundbeck.

74. At the time of the FDA warning, H. Lundbeck revealed that it had placed a prominent suicide warning on the Celexa drug in Europe for years, although no similar disclosure or warning had been made by Defendants in the US for either Celexa or Citalopram.

75. In a Lancet article in April of 2004, British researchers sought to compare the benefits and risks that widely used antidepressants pose for children and adolescents, based on published and unpublished data. They reported that their analysis of the pooled results from two unpublished Celexa trials - the one since published in The American Journal of Psychiatry and the European study cited in the Danish textbook - suggested that Celexa was unlikely to produce a "clinically important reduction in depressive symptoms." "With no good evidence for efficacy and the potential for increasing the risk for suicide, the risk-benefit balance is unfavorable," the researchers reported.

76. Dr. Karen Dineen Wagner of the University of Texas Medical Branch in Galveston, was the lead outside investigator on the study published in The American Journal of Psychiatry.

77. Dr. Adelaide S. Robb of the Children's National Medical Center in Washington who was one of the principal investigators on the US study, stated: "I don't know what the raw data looks like from the European study." She said that she was informed by Forest executives

in 1999 that the European study was under way but that she was never told that it been completed.

78. Both Drs. Robb and Wagner said that Forest did not tell them about the efficacy findings of the European study and that they were not independently aware of them.

79. Recently, Forest has admitted that the antidepressant Lexapro does not appear to help depressed children and adolescents.

80. Forest's acknowledgement, reported by *The New York Times*, is significant since Lexapro contains the same active ingredient as Celexa and the generic Citalopram which is the fourth-leading drug prescribed for pediatric depression.

81. In October 2004, the FDA directed Forest and other manufacturers of antidepressant drugs including Celexa (Citalopram HBr), to revise the labeling for their products to include a boxed warning and expanded warning statements that alert health care providers to an increased risk of suicidality (suicidal thinking and behavior) in children and adolescents being treated with Celexa (Citalopram HBr) and other SSRIs, and to include additional information about the results of pediatric studies.

82. The FDA also informed Forest that it has determined that a Patient Medication Guide (MedGuide), which will be given to patients receiving the drugs to advise them of the risk and precautions that can be taken, is appropriate for these drug products.

83. These labeling changes are consistent with the recommendations made to the Agency at a joint meeting of the Psychopharmacologic Drugs Advisory Committee and the Pediatric Drugs Advisory Committee on September 13-14, 2004.

84. Recently, in May 2007, the FDA proposed that makers of all antidepressant medications, including Celexa (Citalopram HBr), update the existing black box warning on their

products' labeling to include warnings about increased risks of suicidal thinking and behavior, known as suicidality, in young adults ages 18 to 24 during initial treatment (generally the first one to two months).

85. Unfortunately, these warnings came too late to prevent plaintiff's decedent from sustaining serious injuries and death.

86. Defendants have had a continuing duty to disclose the true character, quality, and nature of the drugs that plaintiff's decedent ingested, but instead Defendants concealed it. As a result, Defendants are estopped from relying on any statute of limitations defense. Similarly, Plaintiff may rely on the discovery rule concerning his claim.

87. Moreover, Defendants have an ongoing duty of pharmacovigilance. As part of this duty, defendants are required to continually monitor, test, and analyze data regarding the safety, efficacy, and prescribing practices of their marketed drugs, including Celexa and the generic Citalopram. Defendants continually receive reports from their own clinical trials, practicing physicians, individual patients and regulatory authorities concerning adverse events that occur in patients taking Celexa and the generic Citalopram and Defendants' other marketed drugs. Furthermore, Defendants continue to conduct clinical trials for their marketed drugs long after the drug is approved for use. Defendants have a continuing duty to inform doctors, regulatory agencies, and the public of new safety and efficacy information they learn, or should have learned, about their marketed drugs once that information becomes available to defendants, whether through defendants' clinical trials, other outside sources or pharmacovigilance activities. Specifically, when Defendants learn, or should have learned, of new safety information associated with their marketed drugs, they have a duty to promptly disseminate that data to the public. Defendants also have a continuing duty to monitor epidemiology and pharmacovigilance

data regarding their marketed drugs and promptly report any safety concerns that arise through epidemiologic study or data.

88. Defendants were further negligent and breached this continuing duty of pharmacovigilance with respect to plaintiff's decedent. Defendants, through clinical trials and other adverse event reports, learned that there was a serious problem of suicidality associated with Celexa and the generic Citalopram use and failed to inform doctors, regulatory agencies and the public of this risk. Defendants had the means and the resources to perform their pharmacovigilance duties for the entire time Celexa and the generic Citalopram has been on the market in the United States.

89. Defendants failed to comply with the FDA postmarketing reporting requirements under 21 C.F.R. § 314.80(c) by, inter alia, failing to report each adverse drug experience concerning Celexa and the generic Citalopram that is both serious and unexpected, whether foreign or domestic, as soon as possible but in no case later than 15 calendar days after initial receipt of the information by defendants, failing to promptly investigate all adverse drug experiences concerning Celexa and the generic Citalopram that are the subject of these postmarketing 15-day Alert reports, failing to submit followup reports within 15 calendar days of receipt of new information or as requested by FDA, and, if additional information was not obtainable, failing to maintain records of the unsuccessful steps taken to seek additional information.

90. Defendants' failure to perform adequate pharmacovigilance and failure to comply with the postmarketing requirements of FDA regulations is evidence of Defendants' negligence and constitutes negligence per se.

AS AND FOR A FIRST CAUSE OF ACTION AGAINST THE DEFENDANTS

91. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

92. Defendants are the manufacturers, sellers and distributors of the drugs known as Celexa and the generic Citalopram.

93. For years, Defendants have claimed that Celexa and its generic form Citalopram do not cause suicidal tendencies in patients who are administered Celexa and/or Citalopram.

94. Contrary to these claims, for years, Defendants were aware of clinical trials that showed that children (individuals under the age of 18) who took Celexa and/or Citalopram suffered damaging side effects including agitation, aggression and suicidal tendencies. Additionally, these clinical trials clearly indicated that Celexa and/or Citalopram showed no efficacy for children with major depressive disorder.

95. These clinical trial results were not matched by children given a placebo.

96. Defendants failed to inform the FDA and the public at large of the results of these clinical trials while being aware that Celexa and Citalopram were being prescribed to minor patients.

97. Defendants were careless, negligent, breached its duties and obligations to plaintiff's decedent by various sections of the Restatement of Torts (Second) including § 402A and are liable for causing personal injuries to plaintiff's decedent for the following reasons:

a) selling a product in a defective condition;

b) selling a product which was unreasonably dangerous to the user;

c) selling a product which was not safe for children under the age of 18 to consumer;

d) failing to supply adequate warnings with the product;

e) failing to provide accurate and truthful instructions to be followed with regard to the prescribing of this product;

f) failing to warn children under the age of 18 and their parents/guardians of the dangers inherent in using this product;

g) selling a product wherein it was foreseeable that someone would be injured upon ingesting the medication in question;

h) selling a product which was not safe for its intended use;

i) selling a product which was lacking of one or more elements necessary to make it safe for its intended use;

j) manufacturing a product which was defective and which could cause injury to the user;

k) designing a product which was defective and which could cause injury to the user;

l) distributing a product which was defective and could cause injuries to a user;

m) failing to see that ultimate users were advised of the dangers of said product;

n) failing to exercise reasonable care in the design of this product;

o) failing to exercise reasonable care in the marketing of this product;

p) failing to adequately and properly test said product;

q) failing to use reasonable care under the circumstances;

r) delivering a product which was defective and could cause injury to the user;

s) producing a product which was defective and could cause injury to the user;

t) producing a product with component parts that Defendants knew or should have known increased the risk of harm to the user;

u) supplying a product which was defective and could cause injury to the user; and

v) engaging in other acts regarding the manufacturing, designing, preparing, producing, distributing, advising and selling of Celexa and/or Citalopram as will be learned in discovery.

98. By conducting themselves as aforesaid, Defendants increased the risk of harm, thereby causing the personal injuries and death sustained by plaintiff's decedent.

99. By reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A SECOND CAUSE OF ACTION AGAINST THE DEFENDANTS

100. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

101. Defendants engaged in the conduct described above and intentionally, willfully, recklessly and/or negligently caused plaintiff's decedent's severe emotional distress, prior to his death as set forth in Restatement (Second) of Torts, § 46(1), which ultimately resulted in his death by suicide.

102. The conduct of Defendants in making false statements to the FDA and the general public, knowing Plaintiff and plaintiff's decedent would rely on these statements in deciding whether to allow plaintiff's decedent to take a medication which Defendants knew causes persons to become suicidal and which ultimately and directly resulted in plaintiff's decedent's death by suicide, was extreme and outrageous.

103. Prior to his death, plaintiff's decedent suffered severe emotional distress as a result of the conduct of Defendants.

104. Defendants' actions were willful and/or reckless thus entitling Plaintiff to punitive damages.

105. By reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A THIRD CAUSE OF ACTION AGAINST THE DEFENDANTS

106. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

107. Defendants made the following intentional misrepresentations as established by Restatement (Second) of Torts, § 402B and in:

a) intentionally misrepresenting the risks and efficacy of prescribing Celexa and Citalopram to persons such as plaintiff's decedent;

b) intentionally failing to inform plaintiff's decedent and his wife regarding the fact that clinical trials clearly indicated that Celexa and Citalopram, showed no efficacy in adolescents with major depressive disorder; and

c) intentionally failing to inform plaintiff's decedent or his physicians regarding the fact that clinical trials conducted by defendants showed no efficacy with adolescents and showed an increased risk of akathisia and suicidality.

108. The intentional misrepresentations set forth above were done to induce plaintiff's decedent to purchase and ingest Celexa and Citalopram and to induce plaintiff's decedent's doctors to prescribe Celexa and Citalopram.

109. Such misrepresentations by Defendants concerning the increased risk of suicide associated with the consumption of Celexa and Citalopram constituted an omission of a material fact.

110. The misrepresentations and omissions set forth above were done with the knowledge that the misrepresentations were false when made.

111. Plaintiff's decedent justifiably relied upon the misrepresentations and omissions set forth above in making the decision as to whether plaintiff's decedent would ingest Celexa and Citalopram.

112. As a direct and proximate result of Defendants' intentional and material misrepresentations as set forth above, plaintiff's decedent ingested Defendants' drug which ultimately resulted in his suicide and death.

113. By reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A FOURTH CAUSE OF ACTION AGAINST THE DEFENDANTS

114. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

115. Defendants made the following negligent and reckless misrepresentations as established by Restatement (Second) of Torts, § 525-552, in:

a) negligently and recklessly misrepresenting the risks of prescribing Celexa and Citalopram to persons such as plaintiff's decedent;

b) negligently and recklessly failing to inform plaintiff's decedent regarding the fact that clinical trials clearly indicated that Celexa and Citalopram showed no efficacy in adolescents with major depressive disorder; and

c) negligently and recklessly failing to inform plaintiff's decedent regarding the fact that clinical trials conducted by Defendants showed no efficacy with adolescents and showed an increased risk of akathisia and suicidality.

116. The negligent and reckless misrepresentations set forth above were done to induce plaintiff's decedent to purchase Celexa and Citalopram, to induce plaintiff's decedent to ingest Celexa and Citalopram and to induce his doctors to prescribe it.

117. Such negligent and reckless misrepresentations by Defendants concerning the increased risk of suicide associated with the consumption of Celexa and Citalopram constituted an omission of a material fact.

118. The misrepresentations and omissions set forth above were done with the knowledge that the misrepresentations were false when made.

119. Plaintiff's decedent justifiably relied upon the misrepresentations and omissions set forth above in making the decision as to whether plaintiff's decedent would ingest Celexa and Citalopram.

120. As a direct and proximate result of Defendants' negligent and reckless material misrepresentations as set forth above, plaintiff's decedent ingested Defendants' drug which ultimately resulted in his suicide attempt and death.

121. By reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A FIFTH CAUSE OF ACTION AGAINST THE DEFENDANTS

122. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

123. Defendants expressly represented to the users and their physicians that Celexa and Citalopram were safe and fit for use for the purposes intended, that they were of merchantable quality, that they did not produce any side-effects dangerous to life, and that they were adequately tested and fit for their intended use.

124. Members of the medical community in general, and plaintiff's decedent's treating physicians in particular, relied upon the representations and warranties of Defendants for use and ingestion of Celexa and Citalopram in prescribing, recommending and /or dispensing Celexa and Citalopram.

125. Defendants knew or should have known that said representations and warranties were false, misleading and untrue in that Celexa and Citalopram were not safe and fit for the use intended, and, in fact, produce serious injuries and/or death to the user. As a result of the aforementioned breach of warranties as set forth by Va. Code Ann. § 59.1-196 et seq., plaintiff's decedent was caused to commit suicide.

126. By reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A SIXTH CAUSE OF ACTION AGAINST THE DEFENDANTS

127. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

128. Defendants impliedly represented to the users and their physicians that Celexa and Citalopram were safe and fit for use for the purposes intended, that they were of merchantable quality, and that they did not produce any side-effects dangerous to life, and that they were adequately tested and fit for their intended use.

129. Members of the medical community, and plaintiff's decedent's treating physicians in particular, relied upon the representations and warranties of Defendants for use and ingestion of Celexa and Citalopram in prescribing, recommending and /or dispensing Celexa and Citalopram.

130. Defendants knew or should have known that said representations and warranties were false, misleading and untrue in that Celexa and Citalopram were not safe and fit for the use intended, and, in fact, produce serious injuries and/or death to the user.

131. As a result of the aforementioned breach of warranties by Defendants, plaintiff's decedent was caused to commit suicide.

132. By reason of Defendants' actions as aforementioned, Defendants are liable to the Plaintiff.

133. By reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A SEVENTH CAUSE OF ACTION AGAINST THE DEFENDANTS

134. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

135. At all times hereinafter mentioned, Defendants were under a duty to exercise reasonable care in the design and development of Celexa and Citalopram and, in particular, in the advertising, marketing and promoting Celexa and Citalopram, both directly and indirectly, to ensure that Celexa and Citalopram were not used in the treatment of depression for which they were not effective and to ensure that Celexa and Citalopram were not used in a manner or to treat conditions where Defendants knew or should have known that the user could sustain injuries and harm from the drug.

136. Defendants negligently, recklessly, grossly negligently wantonly and willfully displayed a morally culpable and conscious disregard of the rights of others in that they failed to exercise reasonable care and failed to fulfill the above-stated duty by the manner that Defendants directly and indirectly, advertised, marketed and promoted Celexa and Citalopram for the treatment of depression, even though Celexa and Citalopram had not been scientifically determined to be safe for the treatment of such condition, and even though Celexa and Citalopram were, in fact, not reasonably safe for the treatment of such condition. Furthermore, Defendants failed to adequately warn of the risk of suicide or aggressive, self-destructive behavior of which Defendants knew or should have known about.

137. Defendants were further negligent, reckless, grossly negligent, wanton and willfully displayed a morally culpable and conscious disregard of the rights of others not only by manufacturing, distributing, selling, advertising, marketing and promoting Celexa and Citalopram even though such drug was not safe or effective because it caused or influenced

minors using the drug for any purpose to engage in self-destructive behavior including committing suicide, but also by failing to adequately warn the public of such risks.

138. The aforesaid incident and the injuries sustained by plaintiff's decedent were caused by or were contributed to by the negligence, recklessness, gross negligence, wantonness, willfulness, and conscious and callous disregard of the safety of the public, including plaintiff's decedent on the part of Defendants in the design, manufacture, distribution, advertising, marketing and promoting of Celexa and Citalopram as being safe and effective in the treatment of depression and by inducing the public, including plaintiff's decedent, to believe that Celexa and Citalopram was effective in the treatment of depression.

139. At all times hereinafter mentioned, upon information and belief, the above-described culpable conduct by Defendants was a proximate cause of personal injuries and death sustained by plaintiff's decedent.

140. At all times hereinafter mentioned, plaintiff's decedent did not contribute to his injuries by reason of any negligence or culpable conduct on his part.

141. By reason of the foregoing, plaintiff's decedent was caused to sustain severe and serious personal injuries to his mind and body.

142. By reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR AN EIGHTH CAUSE OF ACTION AGAINST THE DEFENDANTS

143. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

144. State and federal laws and regulations alleged to be violated herein, specifically those regulating the efficacy and distribution of drugs to adolescents and adults, in effect at the time such harm occurred to plaintiff's decedent dictated the standard of care imposed upon Defendants.

145. Defendants' negligent and reckless violation of said laws and regulations deems that Defendants were negligent as a matter of law.

146. By reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A NINTH CAUSE OF ACTION AGAINST THE DEFENDANTS

147. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

148. Defendants' actions as set forth above were intentional, wanton, willful and outrageous. Defendants were grossly negligent, and acted with reckless disregard of and with deliberate, callous and reckless indifference to the rights, interests, welfare and safety of plaintiff's decedent.

149. Defendants' intentional, wanton, willful and outrageous actions consisted of, but are not limited to:

a) intentionally failing to conform to FDA guidelines;

b) intentionally failing to disclose clinical trial data which indicated that Celexa and Citalopram no efficacy in the adolescent population;

c) intentionally failing to disclosed clinical trial data which indicated that Celexa and Citalopram increased the rate of akathisia in the adolescent population;

d) intentionally failing to disclosed clinical trial data which indicated that Celexa and Citalopram increased the risk of suicide and suicidal ideation in the adolescent population; and

e) intentionally and recklessly failing to report to the FDA that patients, prior to plaintiff's decedent, suffered significant liver toxicity which required that the study be put on hold.

150. By reason of the wanton, willful and outrageous conduct of Defendants , as aforesaid, plaintiff's decedent was caused to sustain the catastrophic injuries which ultimately resulted in his commission of suicide and resultant death as described above.

151. By reason of the wanton, willful and outrageous conduct of Defendants, pursuant to the Restatement of Torts, § 908(1), Defendants are liable for punitive damages and relief as this Court deems just.

152. By reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and

exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

AS AND FOR A TENTH CAUSE OF ACTION AGAINST THE DEFENDANTS

153. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein.

154. At the time of the incident and during plaintiff's decedent's consumption of Celexa and Citalopram prior to and until the time of his death, plaintiff's decedent suffered suicidal ideations and apprehension of death during a period of time leading up to the actual commission of suicide.

155. For a period of time leading up to and at the time of the aforesaid suicide, plaintiff's decedent lived and was suffering excruciating mental anguish, severe pain and suffering.

156. By reason of the facts and premises aforesaid, plaintiff's decedent's beneficiaries sustained damages in a sum which exceeds the jurisdictional limits of all lower courts which would have jurisdiction of this matter, and in addition thereto, Plaintiff seeks punitive and exemplary damages against Defendants in an amount to be determined upon the trial of this matter.

WHEREFORE, Plaintiff demands judgment against Defendants as follows:

(1) The sum of $100,000,000.00 on the First Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(2) The sum of $100,000,000.00 on the Second Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(3) The sum of $100,000,000.00 on the Third Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(4) The sum of $100,000,000.00 on the Fourth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(5) The sum of $100,000,000.00 on the Fifth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(6) The sum of $100,000,000.00 on the Sixth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(7) The sum of $100,000,000.00 on the Seventh Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(8) The sum of $100,000,000.00 on the Eighth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action;

(9) The sum of $100,000,000.00 on the Ninth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action; and

(10) The sum of $100,000,000.00 on the Tenth Cause of Action, together with punitive damages and exemplary damages in an amount to be determined upon the trial of this Action, together with the interest, costs and disbursements of this Action.

JURY TRIAL DEMAND

Plaintiff demands a trial by jury as to all issues in the above matter.

Dated: July 10, 2007

FINKELSTEIN & PARTNERS, LLP
Attorneys for Plaintiff
436 Robinson Avenue
Newburgh, NY 12550
(866) 909-8678

BY: _____
ANDREW G. FINKELSTEIN, ESQ.
(AF 1070)

TO: FOREST LABORATORIES, INC.
Defendant
909 Third Avenue
New York, NY 10022

FOREST PHARMACEUTICALS, INC.
Defendant
909 Third Avenue
New York, NY 10022

INWOOD LABORATORIES, INCORPORATED
Defendant
500 Commack Road
Commack, NY 11725

CERTIFICATE/LETTER OF QUALIFICATION
COMMONWEALTH OF VIRGINIA
VA. CODE §§ 6.1-70, 6.1-195.28, 6.1-208.3, 6.1-208.5, 13.1-428, 37.1-134.15, 64.1-122, 64.1-128

Bedford County Circuit Court Court File No.: 05253

I, the duly qualified clerk/deputy clerk of this Court, **CERTIFY** that on the **eighth** day of **September, 2005,**

TEDDY W. HUDDLESTON

duly qualified in this court, under applicable provisions of law, as **ADMINISTRATOR** under Va. Code § 8.01-50

of the Estate of **GARY WAYNE HUDDLESTON** , deceased.

The powers of the fiduciary(ies) named above continue in full force and effect.

$1,000.00 bond has been posted.

Given under my hand and the seal of this Court on

September 8, 2005
DATE

Carol W. Black , Clerk

by _____ Clerk/Deputy Clerk

FORM CC-1625 (w) PC 9/97